

Information about smallpox vaccination for Medical and Public Health response personnel considering smallpox pre-event vaccination

PLEASE READ THIS DOCUMENT THOROUGHLY

COUNSELORS ARE AVAILABLE FOR CONFIDENTIAL ADVICE

Currently, endemic smallpox disease does not exist. However, there is a concern that smallpox virus could be reintroduced intentionally into the world as an act of terrorism. As a medical or public health professional, you are being offered the chance to receive smallpox vaccine now so that you may be better prepared to assist in the medical or public health response to a smallpox outbreak as a designated smallpox responder. Smallpox vaccine is generally considered a safe for most people, but this vaccine can cause life-threatening reactions in some individuals. Depending upon your employer's policy regarding workplace activities that can be undertaken following vaccination, there may be employment and financial risks too. It is important that you read this sheet so that you can be more informed about this vaccine and lessen your risks of having medical, employment, or financial problems if you chose to be vaccinated.

If you need to see your doctor or other designated health professional to talk about the information on this paper, take this paper with you and show it to your doctor.

SMALLPOX VACCINE

The smallpox vaccine contains a virus called vaccinia virus. This virus is related to smallpox virus but does not cause smallpox. Vaccinia virus contained in the vaccine is a live virus however, and can cause problems in some people. Some complications such as inadvertent implantation of virus from the vaccination site onto another area of the body (e.g. the eyelid or eye) can be prevented by diligent handwashing after touching the vaccination site or materials (e.g. bandages) that cover the vaccination site. Another complication, post vaccination encephalitis, is very rare but can occur in anyone getting vaccinated for the first time. More information about smallpox vaccine and some of the complications that can occur from vaccination can be found in the information materials accompanying this document.

People with certain medical conditions are at higher risk for severe skin rashes or other complications from smallpox vaccine. These medical conditions are discussed in further detail below to help you decide if you should receive smallpox vaccine. If you or someone you live with has any of these conditions you should not get smallpox vaccine at this time.

MEDICAL RISKS

People at the greatest risk for complications from the vaccine are those who:

1. Have HIV or AIDS
2. Have weakened immune systems from certain drugs, treatments, or medical conditions (cancer, autoimmune diseases, etc.)
3. Have a history or presence of eczema or atopic dermatitis
4. Have currently active acute or chronic skin conditions (e.g. broken skin from burns, severe acne, psoriasis)
5. Are pregnant
6. Have a severe allergy such as anaphylaxis to a vaccine component (polymyxin B sulfate, streptomycin sulfate, chlortetracycline hydrochloride, neomycin sulfate)

If you fall into any of these groups, you should **not** get the smallpox vaccine at this time. If you have a temporary condition such as broken skin from a burn or are currently pregnant, you may be reconsidered for vaccination once these conditions are no longer present. For other chronic conditions (e.g. vaccine allergy component, weakened immune system, HIV or AIDS), as long as there is no outbreak of smallpox your risk of having a bad reaction from the vaccine would outweigh any benefit you may get from the vaccine. If an outbreak of smallpox occurs you may be re-offered vaccination if you are exposed to smallpox and/or the benefits of vaccination then outweigh the risk that you might have of vaccine complications. If you cannot get the vaccine or chose not to be vaccinated at this time, you should not be on a smallpox response team.

If you are not certain whether you are in any of the groups listed above, you should see your personal doctor who can talk with you and help you get any lab tests you might need.

- **HIV Infection**

About 300,000 people in the US are infected with the HIV virus and do not know it. You can have HIV infection and seem to be completely well. Although you may seem fine, if you have HIV, you are at risk for a bad reaction from the vaccine. If you do not know your HIV status, you should talk with your private doctor to decide if you should be tested before volunteering to get vaccinated. People with conditions such as HIV or AIDS that can suppress their immune system are at higher risk for having a severe skin rash or blood infection from the live virus in the vaccine.

Below is a list of factors that may place you at higher risk for having HIV infection. If any of these apply to you, you should strongly consider being tested for HIV before getting the smallpox vaccine.

1. Use of needles to take drugs, steroids, or anything not prescribed by your doctor
2. Had a blood transfusion prior to 1987
3. Had a transplant such as organ, tissue, or bone marrow
4. Had a graft such as bone or skin from someone other than yourself
5. Come into contact with someone else's blood
6. Had an accidental needle-stick
7. Had sexual contact with someone who has HIV/AIDS or has had a positive test for HIV/AIDS virus
8. Had sexual contact with a prostitute or someone else who takes money or drugs or payment for sex
9. Had sexual contact with someone who has ever used needles to take drugs, or steroids, or anything not prescribed by a doctor
10. For women: Had sexual contact with a man who has ever had sexual contact with another male
11. For men: Had sexual contact with another man

If any of these situations apply to you, now or in the past, you should talk to your doctor about getting tested for HIV before going to the vaccine clinic. You may do this privately. If, after reading this information, or after talking to your doctor, you decide not to get the smallpox vaccine, you do not have to tell anyone why you changed your mind. The decision to get the smallpox vaccine is completely up to you. People may decide not to get the vaccine for many reasons and these reasons are private.

If you decide to get the vaccine, you will go to a designated vaccine clinic. Again you will be told of the risk factors and asked to sign a consent form that says that you understand and accept the risks of smallpox vaccination.

- **Other Conditions that Suppress Your Immune System**

If you have cancers that you are being treated for, you may have a weakened immune system due to the cancer or due to the medications being used to treat the cancer. If you have had a cancer that was treated in the past, such as leukemia or breast cancer, you should check with your doctor to make sure there is no remaining cancer or weakness of your immune system. In addition, some autoimmune diseases like lupus or the medications used to treat these diseases may weaken your immune system. If you have a condition or are on medications that weaken your immune system, you should not be vaccinated with smallpox vaccine. Conditions or medications that weaken your immune system put you at greater risk for severe reactions to the vaccine because your immune system may not be strong enough to mount the immune response needed to contain the live virus in the vaccine.

- **Skin Conditions**

People with some skin problems have a higher risk of bad skin rashes from the vaccine.

1. People with these skin problems **should not** be vaccinated in this vaccine program.
 - Currently active eczema or atopic dermatitis
 - Any history of eczema or atopic dermatitis (even if only during childhood)
2. People with these skin problems (or other problems where there is significant areas of broken skin) should not be vaccinated until the problem is resolved:
 - Impetigo
 - Varicella (chicken pox or zoster)
 - Pityriasis rosea
 - Acute contact dermatitis (e.g. poison oak or ivy)
 - Recent significant burns (> 2 x 2 cm) where skin has not healed completely
 - Current medications that change the immunity or integrity of the skin (prescription acne medication such as retinal, topical immunomodulators such as tacrolimus/protopic or pimecrolimus/elidel)
 - Other conditions that cause significant rash or breaks in the skin
3. People with these skin problems should not be vaccinated until the problem is under good control:
 - Moderate or extensive psoriasis
 - Epidermolysis bullosa
 - Severe acne (face or body)
 - Pemphigus vulgaris

If you are not sure whether you have one of the skin problems listed above, you should see your doctor before going to the vaccination clinic.

Also, if you can answer, “Yes” to the following question you should not be vaccinated at this time:

1. Have you or someone you currently live with ever been diagnosed with eczema or atopic dermatitis (even as a child)? Yes No
2. Have you or someone you currently live with ever had itchy, red, scaly rashes that lasted more than 2 weeks and often came and went? Yes No

If you can answer “Yes” to any of the questions below, you should see your doctor to make sure you don’t have eczema or atopic dermatitis before going to the vaccination clinic.

1. Have you ever had itchy rashes in the folds of your arms/legs? Yes No
2. Did you have skin rashes or food allergies during infancy/childhood? Yes No
3. Has a doctor ever diagnosed asthma or hay fever in you? Yes No

- **Pregnancy**

Women who are pregnant **should not** get the smallpox vaccine while they are pregnant. If they do, they are at risk for miscarriage and stillbirth (giving birth to a dead baby). If you are not sure that you are not pregnant or if you have been having sexual relations with men without using birth control, you should get pregnancy testing from your health care provider or other source **before** going to the vaccine clinic (you may even wish to repeat a home pregnancy test on the day that you are to present for your vaccination). Once you know that you are not pregnant, you must use effective birth control (such as, using the pill, condoms with spermicide, etc...) or avoid sexual relations with men, from the time of your pregnancy test until 1 month after your vaccination. This will help you to be sure that you do not become pregnant during the time when your vaccine site contains live virus.

Women should not become pregnant for one month after getting the vaccine. If you are planning to get pregnant during this period, you should **not** get the vaccine during this program. In addition, because accidental transmission of the vaccinia virus to a pregnant woman could occur and potentially cause problems in the unborn child, if you live in the same household with someone who is currently pregnant, you should **not** be vaccinated until they are no longer pregnant.

- **Severe Allergy to Vaccine Component**

If you have a severe allergy to any of the following vaccine components that causes problems such as difficulty breathing, low blood pressure, or severe rash, you should not get vaccinated in this program.

1. polymyxin B sulfate
2. streptomycin sulfate
3. chlortetracycline hydrochloride
4. neomycin sulfate

If you do not have an allergy to these vaccine components but someone you live with does, you can still be vaccinated. Allergies to these components is only a risk to the person being vaccinated, unlike the risks that are associated with the vaccinia virus itself.

MEDICAL RISKS TO PEOPLE WHO LIVE WITH YOU

Another thing that you need to know is that **if any person living with you has one of the medical problems listed above, they are at risk for medical problems too.** Even though they are not vaccinated, there is a chance that you could spread the vaccine virus from your vaccination site to them. This happens when you touch your vaccination site and touch them without first washing your hands, or they accidentally touch your vaccination site or materials (such as bandages, clothing, or bedding) that have touched your vaccination site.

The safest way to avoid spreading the vaccine virus to others you live with that may have risky medical conditions is to not get the smallpox vaccine. This is the only sure way to avoid exposing the people you live with, who may have high-risk conditions, to the vaccine virus. **If you live with anyone who has any of the conditions above (except for vaccine component allergies) you should not be vaccinated.**

Breast-feeding mothers

There is one addition group of people who should not get the smallpox vaccine in this program:

- Women who are breast-feeding

Babies and children under one year of age are at higher risk for having a reaction to the vaccine virus. That is why we do not vaccinate these little children unless there is an emergency. If you are a woman who is breast-feeding, you should not be vaccinated while you are breastfeeding because the close physical contact that occurs during breast-feeding, increases your chance of accidentally transferring the virus from your vaccination site to your baby.

Now you know that having any of the medical problems listed above can place you at a higher risk for a bad reaction to the smallpox vaccine. And you know that you should see your doctor if you have any concerns about whether or not you have one of the conditions described. **If you know that you or someone you live with has any of the problems listed above, or your doctor thinks that you or someone you live with might have any of the conditions listed above, you should not get the smallpox vaccine.** You can choose not to come to the vaccination clinic for enrollment and vaccination in this program and you do not have to explain to anyone why you have chosen not to be vaccinated.

Your participation in this vaccination program is completely voluntary. We are trying to make this vaccination program as safe as possible. That is why we trying to keep people with certain medical conditions and people living with others who have certain medical conditions from putting themselves or their household members at known risk for a bad vaccine reaction.

EMPLOYMENT AND FINANCIAL RISKS

• Employment Risks

Once you are vaccinated there is a small chance that you could spread the vaccine virus to others that you work with. This might happen if you touch your vaccination site or bandage and touch other people, without first washing your hands. Some employers will want to be very careful about letting you work. They may ask you to wear a special dressing on your vaccine site until your scab falls or may decide to reassign you to different job duties until your site is completely healed. Although the Advisory Group for Immunization Practices (ACIP) does not think that furlough is necessary, your employer may even decide to ask you to stay home (furlough) until your vaccine site scabs over or the until the scab falls off. There is currently no Federal program or regulation in place to be sure that your employer will continue to pay you if you are put on furlough following vaccination.

It is very important that you check with your employer before getting the vaccine to find out what they will require of you if you get vaccinated and how they will pay you or otherwise compensate you if they ask you not to work.

• Financial Risks

Although rare, bad reactions to the vaccine can occur. If you or someone you live with has a bad reaction, the treatments for these reactions can be very expensive. The Centers for Disease Control and Prevention (CDC) will provide the special drugs needed to treat certain reactions free of charge. However, the CDC will not cover the cost of hospitalization, medical consultations, other possible medical expenses, or lost wages. Currently there is no Federal program to cover the cost of hospitalization, medical consultations, other medical expenses, or lost wages. Your insurance company, Medicare, Medicaid, the Workman's Compensation Program, may have to pay these expenses. There is no guarantee that your medical bills will be paid by any of these groups and you may end up being responsible.

Another financial burden you may have is lost wages. If you are out of work because you are sick from a reaction to the vaccine you may find that your employer will not pay you. There is no program in place that can guarantee you the money you may lose in wages.

It is possible that if someone you live with becomes sick because you have spread the vaccine virus to them, that they will have problems with medical expenses and lost wages too. There is currently no designated program in place to pay these expenses.

It is important that you check with your employer (Workman's comp medical expense coverage and lost wages compensation) or your private insurance company (medical expense coverage) to determine who would be responsible for coverage for both of these possible financial burdens (medical expenses and lost wages) before you decide to get the smallpox vaccine.

You should inquire at the time of your vaccination appointment whether a designated program is available for compensation of medical expenses resulting from an adverse reaction to the vaccine and/or compensation for lost wages resulting from injury due to the vaccine.

Summary

You have just read about the medical, employment and financial risks of getting the smallpox vaccine. Please think them over carefully. Get all the information you need before coming to the clinic to get the vaccine. See your doctor, get whatever lab tests you need, and talk to your employer.

If you decide to come back to the clinic to get the smallpox vaccine, you will be asked a series of medical questions similar to the checklist that you received in the pre-program packet to be sure that you know it is safe for you and the people you live with, for you to get the vaccine.

If you have any of the risky medical problems listed in this information sheet, you will not be able to get the smallpox vaccine or be a smallpox response team member. However, if there is ever a smallpox outbreak, the rules for getting the smallpox vaccine may be different. Then if you need the vaccine, it will be made available to you.